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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,271	07/31/2003	Michael P. Whitman	11443/155	5470
26646	7590	09/28/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			ADAMS, AMANDA S	
			ART UNIT	PAPER NUMBER

3731

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,271	Applicant(s) WHITMAN ET AL.	
	Examiner Amanda Adams	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/9/05, 5/24/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 21-26, and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Avni et al (US 6,447,444).

3. Regarding claims 1-5, 34- 38 Avni et al disclose the invention substantially as claimed including a tubular member with a proximal and a distal end, the distal end being adjustable between a first position, in which it has a conical or tapered shape, and a second position (compare distal ends of tube in figs. 3a and 3b), wherein the distal end has a smaller diameter than the proximal end when in the first position, the diameter of the distal end is greater than that of the proximal end when in the second position (col. 8, lines 50-65), and the distal end includes a slit such that the diameter of the distal end is adjusted to the second position by opening of the slit (slit being the portions between the leaves). Avni et al also teach that the distal end diameter is adjusted by stretching a stretchable material (col. 9, lines 33-36).

4. Regarding claims 21-26, Avni et al discloses the method substantially as claimed including insertion of the distal end into an orifice and adjusting the distal end into a second position (col. 8, lines 49-64), inserting an element that is a surgical device through the tubular member (col. 9, lines 66-67), and adjusting the diameter of the distal

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end so that it is greater in the second position than in the first position and this is done by stretching the leaves from each other at the distal end, which also involves opening of the slits between the leaves at the distal end (col. 8, lines 57-61).

5. Claims 11-16, 19, 20, 28, 29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Coe et al (US 6,167,315).

6. Regarding claims 11-16, 19, and 20, Coe et al discloses the invention substantially as claimed including a tubular member with a distal end, and a distal portion with a proximal end that is configured to be detachably secured to the distal end of the tubular member, and is selectively detachable (col. 6, lines 30-52), the distal end of the distal portion having a smaller diameter than the rest of the distal end (fig. 2 [24]), the proximal end of the distal portion contracting when detached so as to have a smaller diameter (col. 9, lines 35-40), an annular groove in the proximal portion of the distal end so that the two parts can be detachably secured (col. 6 line 33, the press-fit mechanism [26]), and also comprising a tubular insertion device configured to be insertable through the tubular member, the tubular insertion device configured to detach the distal portion from the tubular member when it is inserted into the tubular member (col. 8, lines 62-67, the hypotube [30] as the inner tubular member), the proximal end of the contracting so as to have a smaller diameter when it is detached from the tubular device, so that it is capable of being pulled through the tubular insertion device (col. 9, lines 37-40; the ability to be restretched when reattached means that it must contract when detached). Further, Coe et al disclose a device that is capable of introducing a surgical device into an orifice (fig. 1 and 2).

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7. Regarding claims 28, 29, and 33, Coe et al disclose the method substantially as claimed above further including inserting the distal end of the tubular device into an orifice, selectively detaching the distal portion, the distal portion contracting once it is detached, and detaching the distal end by inserting a tubular device through the tubular member to contact an inner wall of the distal portion (col. 8, lines 56-66 and col. 9, lines 30-40).

8. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Selmon et al (US 6,599,304).

9. Regarding claims 1-8, Selmon et al disclose the invention substantially as claimed including a tubular member with a distal and proximal end, the distal end being adjustable between a first position and a second position, the first position having a distal end smaller than the proximal end (fig. 5) and the second position having the distal end diameter greater than the distal end diameter of the first position (fig. 6), wherein a portion of the distal end is stretchable and adjustable to the second position by stretching, and adjustable by opening of a slit at the distal end (fig. 15A [310]). Selmon et al also disclose a plurality of holes (fig. 17A and 17B [366]) adjacent to the slit at the distal end and a string ([355]) through the holes wherein the opening of the slit is controlled by movement of the string (compare figs 17A and 17B), and an actuator such that one end of the string is attached to an actuation device (fig. 1 [26]).

Claim Rejections - 35 USC § 103

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selmon et al (US 6,599,304) in view of Ko (US 5,354,302).

12. Regarding claim 9, Selmon et al disclose the invention substantially as claimed above but fail to disclose a particular actuator. However, Ko teaches an actuation device for a similar surgical tool wherein the actuator is a ring (fig. 1, ring handle is below ref num 54). A ring-shaped actuator is an easy to grip object for the surgeon, minimizing surgical error during a procedure that uses this device. Therefore it would have been obvious to have a ring shaped actuator.

13. Regarding claim 10, due to lack of criticality in the specification, having both ends of the string attached to the actuator was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to having only one end of the string attached. Therefore, it would have been obvious to attach both ends of the string to the actuator because it is capable of working equally as well as attaching only one end of the string to the actuator.

14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Avni et al (US 6,447,444) in view of Selmon et al (US 6,599,304).

15. Avni et al discloses the method substantially as claimed above but fails to disclose opening of the slit by moving, via an actuation device, a string attached to the

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slit. However, Selmon et al teach opening of the slit by moving, via an actuation device, a string attached to the slit (col. 19, lines 12-16). This string and actuator provide a convenient method of actuation and conserves space, reducing the volume of the surgical device that is inserted into the orifice. Therefore it would have been obvious to use a string and ring shaped actuator to control the opening of the slit located at the distal end of the device.

16. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coe et al (US 6,167,315) in view of Moll et al (US 5,522,790).

17. Coe et al disclose the invention substantially as claimed except for failing to disclose a recovery device that is a string attached to an inner wall of the distal portion capable of drawing the distal portion through the tubular member. However, Moll et al teach a recovery device that is a string attached to an inner wall of the distal portion capable of drawing the distal portion through the tubular member (figs. 13A-13D). This removal device conserves space, reducing the volume of the surgical device that is inserted into the orifice. Therefore it would have been obvious to have a string attached to the distal end as a removal device.

18. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coe et al (US 6,167,315) in view of Moll et al (US 5,522,790).

19. Coe et al disclose the method substantially as claimed above further including inserting an element through the tubular member (inner hypotube [24]) but fails to disclose the steps of withdrawing the distal portion through the tubular member, and inserting a surgical device through the tubular member. However, Moll et al teach a

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similar method wherein the distal portion of the device is withdrawn through the tubular member (col. 3, lines 44-47) and a surgical device is inserted through the tubular member (col. 14, lines 50-55). Because the device of Coe et al is capable of these steps, it would have been obvious to insert a surgical device along with the hypotube and to withdraw the distal end so that it does not create an obstacle for the surgical device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ASA 8/21/06


GLENN K. DAWSON
PRIMARY EXAMINER